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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/631,923	07/31/2003	Raya Levin	4517-4002	9017

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EXAMINER

RAETZSCH, ALVIN T

ART UNIT	PAPER NUMBER
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1754

DATE MAILED: 08/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/631,923

Applicant(s)

LEVIN ET AL.

Examiner

Alvin T. Raetzsch

Art Unit

1754

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 1-22 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

1. Newly amended claim 25 is now a linking claim with restricted groups I & II.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. **Claims 23-25** are rejected under 35 U.S.C. 103(a) as being unpatentable over Phadke et al. (5,302,396) in view of the Carrier fluid bed product document (1992).

Phadke teaches a granulation comprising high shear mixing of a calcium carbonate composition and drying with a tray drier. A horizontal fluid bed dryer is not used. Carrier Vibrating Equip., Inc., sells horizontal fluid bed dryers for use in pharmaceuticals and many other powder/pellet type applications. It would have been obvious to one of ordinary skill in the art at the time of the invention to use a horizontal fluid bed dryer of Carrier in the process of Phadke in order to, as explained in the Carrier document, improve drying efficiency and uniformity of the product.

3. **Claims 23-25** are rejected under 35 U.S.C. 103(a) as being unpatentable over Gennaro (Remington: The Science and Practice of Pharmacy) in view of the Carrier fluid bed product document (1992), taken with the Applicant's admissions.

Gennaro teaches that it is common in the art of granulation processes to use high-shear mixing and fluid bed drying. The use of specific types of fluid bed dryers, such as horizontal, is not discussed. The Carrier document, which predates the Gennaro reference, shows that the use of horizontal fluid bed dryers was known in the art of pharmaceuticals and tablet making. It therefore would have been obvious to one of ordinary skill in the art at the time of the invention to use a horizontal fluid bed dryer in such granulation processes in order to, as explained in the Carrier document, improve drying efficiency and uniformity of the product.

While Gennaro does not specifically teach the use of calcium carbonate in the granulation and tablet making processes, it is old and known in the art, as discussed by the Applicant in the current disclosure (Background) that many supplements include the use of calcium carbonate in the composition thereof. It would have been obvious to one of ordinary skill in the art at the time of the invention to use calcium carbonate in

the processes taught by Gennaro in order to include calcium in supplement to take advantage of its known health benefits.

Response to Arguments

4. Applicant's arguments filed 5/18/06, with respect to Gennaro not anticipating the use of a horizontal fluid bed dryer have been fully considered and are persuasive. The 102 rejection based thereon has been withdrawn.

Applicant's additional arguments filed 5/18/06 are not persuasive:

1. The Applicant states in the Remarks and the Declaration filed that the teaching of "fluidized bed" in Gennaro would not have been recognized by one skilled in the art to include horizontal fluid bed dryers. While Gennaro does show figures of vertical fluid bed dryers, it is not explicitly stated that any specific configuration is intended by the teaching. The Carrier document, which predates the Gennaro reference by several years, shows that horizontal fluid bed dryers were in fact known and used in the art prior to the Gennaro teaching. Therefore, it can be reasoned that Gennaro's teaching of using fluid bed dryers is not restricted to any specific configuration.

2. The Applicant also argues unexpected results from using a horizontal dryer. As evidence the Applicant points to Examples I-VI of the application and the product density results therein. To what products are these being compared? These are the only examples in the application. No comparative examples using other dryer configurations are given. In addition, the originally filed disclosure teaches or implies that horizontal dryers are preferred or give unexpected results. The application lists several dryer types, including vertical fluid bed, as being acceptable and it is not taught that the different types affect different properties critical to the invention. The examiner is not stating that all factors in attaining unexpected results must be completely disclosed upon filing, but merely that some indication of the cause of such results or the improvement over the prior art is mentioned. The Applicant clearly discloses their improvements over prior art; there is no indication, however, that dryer type is such an improvement. Further, the horizontal dryer that the Applicant employs (Carrier D/C

1260S - see page 4) is not new in the art as discussed above. With regard to any arguments addressing dryer vibration, the aid of vibration in drying is neither claimed nor supported in the original disclosure (the only mention of vibration is with respect to the feeder, not the dryer).

3. In response to arguments regarding "high density", this recitation has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). In the present case the process steps are able to stand alone and do not, as claimed, make a product of any particular density. In addition, the use of the term "high" is a general term and no specific value is assigned in the specification aside from preferred values.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alvin T. Raetzsch whose telephone number is 571-272-8164. The examiner can normally be reached on 9-5 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Stanley Silverman can be reached on 571-272-1358. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ATR 



STUART L. HENDRICKSON
PRIMARY EXAMINER